K013931
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MAR 2 7 2002

510(k) Summary

Submitter Information:

Submitter:	SeQual Technologies, Inc. 11436 Sorrento Valley Road San Diego, CA 92121
Contact:	Pam Jackson, Director of Portable Systems
Phone:	(858) 202-3100
FAX:	(858) 558-1915
Date of Summary:	November 1, 2001

Device Name:

Proprietary Name:	Model 1000 OMNI Portable Oxygen Concentrator
Common Name:	Oxygen concentrator
Classification of Device:	Portable Oxygen Generator (73 CAW) as per 21 CFR 868.5440

Predicate Device Equivalence:

SeQual Technologies is claiming substantial equivalence to the SeQual Technologies Model 6400-OM Oxygen Concentrators, 510(k) Number K003472 and the Sim Italia, Travelair Portable Oxygen Concentrator, 510(k) Number K963042.

Description of Device:

The SeQual Model Number 1000 OMNI Portable Oxygen Concentrator is a 3 Liter per minute (LPM) continuous flow and 6 LPM demand flow oxygen concentrator that is of the pressure swing adsorption (PSA) type. The OMNI Portable Oxygen Concentrator operates from AC power, DC power or rechargeable batteries. This device delivers supplemental oxygen for patients through the molecular sieve beds and is designed to conserve the use of oxygen while operating in a demand flow mode. During the demand flow mode, oxygen is delivered to the patient through a demand flow valve when the start of inhalation is detected. This conserving feature is similar to the Sim Italia Travelair.

Oxygen Concentrators are prescription devices designed to provide an inexpensive supply of supplemental oxygen without a continuous source of liquid or gaseous purified oxygen. Oxygen concentrators are not life-supporting nor life sustaining devices. An oxygen concentrator is a device that draws in normal ambient room air, filters it and separates the nitrogen from the air under pressure, allowing only oxygen and trace gases to pass through to the oxygen outlet connection to the patient. The nitrogen enriched air is then exhausted back into the room. The air we encounter in nature is a mixture of roughly 78% nitrogen, 21% oxygen and 1% other trace gases..

The Model Number 1000, OMNI Portable Oxygen System consists of pneumatic and electrical components. The system has 5 major pneumatic components: inlet filtration, air compressor and heat exchanger, Synthetic Zeolite molecular sieve beds with a distribution valve module, outlet filtration, and flow delivery and measurement components. The electrical system consists of: motor controls, power sources for AC and DC power, rechargeable batteries, sensing systems to measure pressure, temperature, flow and oxygen concentration, and a software controlled user interface.

The unit is double insulated and uses a two-conductor power cable. In the event of a malfunction, the unit will activate visual and audio alarms and if, necessary, shut down. Device monitoring circuits are included to measure oxygen concentration, flow rates, battery capacity and internal temperatures.

The major changes to the device have been the reduction in the size of the molecular sieve tanks and the capability to operate on rechargeable batteries.

Intended Use:

Oxygen concentrators are intended to provide supplemental oxygen to persons requiring low flow oxygen therapy. The patient typically receives the oxygen through a nasal cannula. The device delivers flow rates between .5 and 6 liters per minute of oxygen over 90% concentration. It is used at a patients home or for their portable needs outside the home and can also be used in

institutions such as nursing homes or sub-acute care facilities. Oxygen concentrators are not considered life supporting nor life sustaining. The device has no contraindications.

Technological Characteristics:

The Model 1000, OMNI Oxygen System operates comparably to the SeQual Integra concentrators with the addition of a demand flow valve delivery system and with the capability of being operated from various power sources, AC, DC and rechargeable batteries. The technology employed to generate the oxygen is well established, therefore, raises no new questions of safety and effectiveness. The technology has been used in the predicate devices as well as other legally marketed products.

Performance Data:

The results of the oxygen concentration testing and thorough series of testing, ISO 8359 and ASTM F1464 will confirm that the device will meet the specifications and will be substantially equivalent to the predicate devices.

Conclusion:

Based on the design, performance specifications, testing and intended use, the Model 1000, OMNI Portable Oxygen Concentrator will be substantially equivalent to the currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2002

Ms. Pamela J. Jackson
Director, Quality and Regulatory Affairs
SeQual Technologies, Inc.
11436 Sorrento Valley Road
San Diego, CA 92121

Re: K013931
OMNI Oxygen System, Model 1000
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II (two)
Product Code: 73 CAW
Dated: March 18, 2002
Received: March 19, 2002

Dear Ms. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

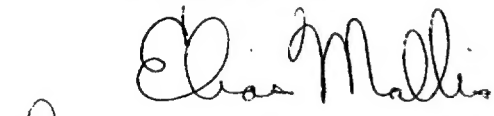
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Ver/ 3 – 4/24/96

Applicant: SeQual Technologies Inc.

510(k) Number (if known): K013931

Device Name: Omni Oxygen System

Indications For Use:

The Model 1000 Omni Oxygen System is indicated for the administration of supplemental oxygen. The device is not intended for life support nor does it provide any patient monitoring capabilities.

Prescription legend required.

Division of Cardiovascular & Respiratory Devices
510(k) Number K013931
Elaine Miller

Prescription Use ✓ Emiller
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Int510k/induse